UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	MDL NO. 2272
This Document Relates to All Cases	)	Master Docket Case No. 1:11-cv-05468
	)	Hon. Rebecca R. Pallmeyer

ZIMMER ENTITIES' POSITION STATEMENT
FILED PURSUANT TO COURT'S NOVEMBER 10, 2011 ENTRY

As the Court instructed during the November 10, 2011, status conference, the Zimmer Entities[1] respectfully submit this brief summary of their positions, with the broader introduction to the scientific issues to be presented at the Court's conference on January 12, 2012.

I. Knee Replacement Surgery Has A History Of Success, But Success In Any One Patient Depends On Surgical And Patient-Specific Factors.

Knee replacement surgery – also known as total knee arthroplasty (TKA) – can restore function and mitigate pain for patients with diseased knee joints. The primary reason for knee replacement surgery is to replace joints damaged by arthritis. In most cases, knee replacement surgery is successful, the patient experiences less pain, and much of the patient's previous function is restored. However, every TKA carries risks, including the risk that the implant will loosen and require replacement surgery (also known as "revision surgery").

[1] Defendants in these actions are Zimmer, Inc., Zimmer Holdings, Inc., Zimmer Orthopaedic Surgical Products, Inc., Wilson/Phillips Holdings, Inc., d/b/a Zimmer Wilson/Phillips, Orthopaedic Technologies, LLC, d/b/a Zimmer Tri-State (incorrectly named as (1) Zimmer Tri-State d/b/a Tri-State Orthopaedic, (2) Zimmer Tri-State d/b/a Zimmer, Inc., and/or (3) Zimmer Tri-State d/b/a Tri-State Orthopedic), K. Michael Melia, d/b/a Zimmer Melia & Associates, Inc. (incorrectly named as Zimmer Melia & Associates, Inc.), Zimmer Orthobiologics, Inc., Zimmer Surgical, Inc., and Zimmer US, Inc.

The human knee is one of the most heavily loaded joints in the body. Walking, squatting, rising from a chair, stair climbing or descent, and other activities impose forces across the knee joint from three to seven times body weight. These forces, combined with a variety of patient, surgical, and biological factors, impact the success of TKA.

Regardless of the brand or type of knee implant selected, success of TKA depends on multiple variables. Surgical factors influencing success include the selection of appropriate implants of the correct size and shape, making precise bone cuts to fit the implants, removing an appropriate amount of bone, achieving correct alignment of the components, proper application of bone cement for cemented implants, proper cleaning of the implant site, and proper post-surgery care and rehabilitation. In addition, there are important patient and biological variables that influence TKA success, including whether the patient develops an infection or adverse reaction to the surgery or implant, as well as patient weight, height, age, gender, quality of bone stock, body mass index, and activity level. Much further down the list of variables influencing success is the implant design.

As a consequence, revision surgery can be necessary for a wide range of reasons, and a potential defect in a knee implant is far from the most common on the list.

II. Flex Components Allow Safe Flexion In Patients Able To Achieve Deep Flexion. Flex Components Do Not Create Deep Flexion.

Zimmer introduced the first *NexGen* branded knee implant in 1995, after more than two decades of experience with modern knee replacement products. After widespread use of the *NexGen* CR and LPS Femoral Components, surgeons noted that some patients were able to achieve “deep” or “high” flexion (i.e., flexion over 120 degrees) post-operatively.

Deep flexion is particularly common in Asia and the Middle East because cultural and religious activities demand it beginning in early childhood. However, surgeons and industry

experts noted that patients able to achieve deep flexion with traditional knee implants faced the risk of damaging their knee implants when engaged in frequent deep flexion. As such, Zimmer, Inc. ("Zimmer"), designed a "Flex" version of some of its *NexGen* femoral components to prevent that risk of damage. The *NexGen* Flex Femoral Components include design modifications intended to reduce the risk of premature wear or damage to the implants should a patient repeatedly achieve deep flexion.

No artificial knee component *creates* deep flexion. Flexion depends primarily on the patient's pre-operative flexibility, with patient weight, body habitus, and other factors influencing the post-operative outcome. A non-flex knee implant can often bend just as far as a flex knee implant. *NexGen* Flex Femoral Components are designed to allow safe flexion without damage to the components when patients achieve flexion greater than 120 degrees.

The geometries of the CR Flex and LPS Flex Femoral Components, which now have more than seven and ten years of worldwide successful clinical experience respectively, were adapted from their standard CR and LPS predecessors. Zimmer's design modifications included (1) lengthening and reshaping the femoral condoyles of the CR and LPS to work better in deep flexion, (2) reshaping the front of the tibial component to accommodate the tendons on the front of the knee and natural knee rotation during deep flexion, and (3) reshaping the polyethylene tibial articular surface to better hold the femoral component in place during deep flexion.

III. The 5950 MIS Tibial Component Is Not A Flex Component And Should Not Be In MDL-2272.

By virtue of the Panel's August 8, 2011, order, this MDL includes matters involving the alleged failure of a tibial component called the "MIS Total Knee Procedure Stemmed Tibial Component Fixed Bearing Precoat," which is also known as the MIS Tibial

Component or "5950." (MDL No. 2272, August 8, 2011, Transfer Order, Doc. 110, p. 2, n.3.) This is the sole tibial component considered by the Panel. However, it is the Zimmer Entities' position that cases involving the 5950 MIS Tibial Component should not be part of this MDL, as they are wholly unrelated to Zimmer's flex technology. At the appropriate time, Zimmer will ask this Court to recommend remand of any matters involving a failed 5950 MIS Tibial Component.

The 5950 MIS Tibial Component can be implanted with any number of flex *or* standard femoral components. However, this component is different from the flex femoral components discussed above, most notably because *it is used to treat an entirely different bone within the knee*. The femoral components discussed above are used to treat the femur, while the 5950 MIS Tibial Component is used to treat the tibia. And, unlike femoral components, the 5950 MIS Tibial Component has no flex or non-flex version, it works with multiple femoral components (both flex and non-flex).

Zimmer released the 5950 MIS Tibial Component in 2005. Designed for implantation through a small incision, the 5950 MIS Tibial Component features a short, broad keel on the bottom of the tibial baseplate. Side fins extend from each side of the keel, which further engage the tibial bone. In addition, Zimmer offers stem extensions that can be added to the keel to provide surgeons the intraoperative flexibility of adding a stem to increase implant stability.

Between 2008 and 2010, Zimmer became aware of three clinical outcome studies that reported early loosenings of implanted 5950 MIS Tibial Components. Zimmer investigated, and in 2010 it voluntarily elected to update the Surgical Technique and Package Insert to emphasize the importance of adequate visualization and correct cementing technique, while making the use a drop down stem extension mandatory. On April 26, 2010, Zimmer issued a letter to surgeons, advising them of the enhanced labeling for the 5950 MIS Tibial Component, and Zimmer further revised the Surgical Technique and Package Insert to reflect its instruction changes.[2] Zimmer's change in the instructions for the MIS Tibial Component were wholly unrelated to use of the component with any flex (or non-flex) femoral component.

IV. All *NexGen* Components Have Documented High Success Rates.

Broad national registry data covering all *NexGen* branded products reflect industry-leading performance. The Australian Registry is one such registry. It identifies revision rates in Australia for orthopaedic implants by manufacturer, brand, and design. For example, according to the 2011 Australian Registry Report, the *NexGen* CR Flex Femoral Component has second lowest revision rate – 2.1% – of all 27 different brands of cemented femoral components for which 5-year data is reported. Likewise, the cemented *NexGen* LPS Flex Femoral Component had a revision rate of 4.2% at 7 years, well within the range of other clinically successful designs. The Australian Registry also reports that, for the past four years recorded (2007-2011), the *NexGen* CR Flex and LPS Flex Femoral Components were among the ten most widely used primary total knee replacement components implanted in Australia. The Australian Registry captures the outcomes of over 20,000 patients who received either a *NexGen*

[2] The FDA posted notice of Zimmer's letter to surgeons on its website on September 13, 2010, and classified the action as a "Class II Recall." A "Class II Recall" is defined by the FDA as "a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." 21 C.F.R. § 7.3(m)(2).

CR Flex or LPS Flex Femoral Component. The Australian Registry data strongly supports the conclusion that the *NexGen* CR Flex and LPS Flex Femoral Components, like the previous generation of *NexGen* knees, are safer and more successful than competing designs.[3]

V. Zimmer Thoroughly Tested The NexGen Flex Products And The 5950 MIS Tibial Component.

Zimmer conducted rigorous testing and analysis to verify that the *NexGen* Flex products are, in fact, capable of withstanding flexion above 120 degrees. Zimmer's testing augmented the extensive testing Zimmer performed during the development of the original *NexGen* femoral components included, but was not limited to:

- Anterior Lift-Off Testing (to test the articular surfaces in conditions that simulate deep flexion);
- Contact Area and Conformity Analysis (to ensure that the contact area was maximized during deep flexion);
- Posterior Edge Loading Testing (to determine whether the tibial articular surface would survive the anticipated flexion activities for a lifetime of 20 years);
- Femoral Component Strength Analysis (to verify the strength of CR Flex Femoral Component condyles);
- Patelleofemoral Joint Compression analysis (to estimate the patellofemoral joint compression for deep flexion squatting);
- Articular Surface Spine testing (to test the strength of the spine on the articular flexion); and
- Posterior Lift-Off Testing (to test the fixation of the plastic articular surface).

Available independent clinical data, coupled with the extensive analysis and testing during development, demonstrate the safety of Zimmer's *NexGen* Flex Femoral Components and the 5950 MIS Tibial Component.

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[3] Although no U.S.-based orthopedic registry presently exists, other national databases are consistent with the Australian Registry data.

VI. Plaintiffs' Stated Defect Theory Is Not Supported.

In the plaintiffs' briefing before the Panel, the plaintiffs summed up their defect theory as follows: the "common underlying theory in all of these cases is that the engineering changes intended to provide additional flexion is causing premature failure more often than in the standard flex implants and provides no additional benefit to the patient." (MDL No. 2272, Reply in Supp. Mot. to Transfer, Doc. 58, p. 2.)

The plaintiffs rely heavily on a June 19, 2010, New York Times article about an oral presentation given by Richard Berger, M.D., to support their theory. According to the plaintiffs, the New York Times article "detail[ed] a high rate of failure among components making up the Zimmer NexGen knee implant devices, used in hundreds of thousands of knee replacement surgeries worldwide." (MDL No. 2272, Br. in Supp. Mot. Transfer, Doc. 1-1, p. 1.) However, the plaintiffs hold Dr. Berger's presentation out for far more than it is worth in multiple respects. First, the comments expressed during Dr. Berger's presentation included the personal experiences of Dr. Berger and one colleague, Craig Della Valle, M.D., with 108 cases. Those experiences related only to the porous, i.e. uncemented, CR Flex Femoral Component. Dr. Berger's presentation has never been peer-reviewed or published. Moreover, evidencing the narrow boundaries of his report, Dr. Berger continues to this day to use the cemented (precoat) version of the *NexGen* Flex Femoral Components in hundreds of patients each year.

Second, many peer-reviewed scientific papers reveal excellent clinical results for *NexGen* flex femoral components. In stark contrast, the plaintiffs rely heavily on a handful of articles that report isolated results. One such study by Sung-Do Cho, M.D., evaluated 218 cemented LPS Flex Femoral Components in 166 Korean patients, for whom squatting, kneeling, and sitting on the floor were normal daily activities. Cho, *et al.*, *Three-to-Six Year Followup Results after High-Flexion Total Knee Arthroplasty: Can We Allow Passive Deep Knee Bending*

(2011). After an average follow-up time of 4 years, 3.2% of the knees had been revised – i.e. *six* knees. All six of the revised knees belonged to patients exhibiting flexion with a mean range of motion of 142 degrees. The authors fully acknowledged, however, that these patients were at a significant risk for loosening, regardless of the implant selected, given their flexion. Moreover, the authors attributed the loosenings to patient non-compliance with surgeon's warnings concerning high load, deep flexion activities. And, after forbidding these daily activities, the authors reported that there were no other cases of early loosening.

Another Korean study frequently cited by the plaintiffs reported a 21% remission rate for LPS-Flex Knees implanted in only 47 patients at 2 years, and 38% of the knees showing signs of loosening at 2.7 years. Han, *et al.*, *High Incidence of Loosening of the Femoral Component in Legacy Posterior Stabilised-Flex Total Knee Replacement* (2007). However, the authors conceded the study's "inherent weaknesses because of its retrospective, non-comparative design and the relatively small number of patients." *Id.* at 1460. The authors also noted that the small, single surgeon sample (72 knees in 47 patients implanted by only one surgeon) involved many patients following "a traditional Korean lifestyle . . . and demanded weight-bearing high-flexion activities in daily life." *Id.* One of the United States' leading orthopaedic surgeons, Giles R. Scuderi, M.D., of the Insall Scott Kelly Institute in New York, found the *Han* study to be inherently unreliable because it is a retrospective study in a small group of patients with no control group for comparison. Dr. Scuderi found it disturbing that "the authors are placing blame on the implant design and the degree of flexion achieved by this limited cohort of patients," noting as follows:

> The early failure of fixation is probably related to either errors in surgical technique or more likely errors in cement technique. The results in this study are contrary to my own experience with this prosthesis, and I find it incredible that the authors place blame on

> the implant design. I refer the authors to several publications supporting high flexion knee designs, including the Legacy high flexion posterior stabilized prosthesis. The design features of the LPS-Flex prosthesis have undergone extensive scientific testing and are based on sound principles.

Giles Scuderi, M.D., *Electronic Letter, Successful results with a high flexion posterior stabilised knee prosthesis,* J Bone Joint Surg Br Online, 21 Dec. 2007, *available at* http://web.jbjs.org.uk/cgi/eletters/89-B/11/1457#1716.

In short, the literature the plaintiffs cite does not support their defect theory.

VII. Numerous Other Scientific Papers Reflect Excellent Performance Of NexGen Flex Components.

The safety and efficacy of the *NexGen* product line, including the seven components at issue in this MDL, are backed by overwhelming independent data. The technology is complex, but the proof is straightforward. As the Zimmer Entities will demonstrate during the pendency of this litigation, none of its *NexGen* components are defective.

Dated: January 5, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on January 5, 2012, a copy of the foregoing Zimmer Entities' Position Statement Filed Pursuant To Court's November 10, 2011 Entry was filed electronically. Parties may access this filing through the Court's system. I further certify that on January 5, 2012, a copy of the foregoing Zimmer Entities' Position Statement Filed Pursuant To Court's November 10, 2011 Entry was sent by first-class United States mail, postage prepaid, upon the following:

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